

PATENT  
2503-1073

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Francesco DI PIERRO

Conf. 8169

Application No. 10/477,923

Group 1617

Filed November 18, 2003

Examiner D. Claytor

PHARMAECUTICAL AND/OR COSMETIC COMPOSITIONS  
FOR THE TREATMENT OF LOCALISED ADIPOSITIES AND  
CELLULITE

DECLARATION UNDER RULE 132

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Francesco DI PIERRO, hereby declare as follows:

I am the same Francesco DI PIERRO names as the inventor of the above-identified application. My relevant background and experience are set forth on the attached c.v.

I declare that one skilled in the art would not have found obvious the claimed invention in view of the references cited in the Official Action. I have compared the effects of a composition prepared in accordance with Example 2 of the present specification on cellulite to compositions which contain one of the active ingredients recited in the claimed composition. The experimental results are as follows:

The effect of the composition of Example 2 was evaluated on groups of 10 women suffering from cellulite, of age comprised between 24 and 45, weighing  $65.4 \pm 2.3$  kg on average. Each group was treated with the following

compositions:

Group 1 = placebo

Group 2 = *Escin/beta-sitosterol* complex with phospholipids

Group 3 = *Ginko biloba* dimeric fraction complex with phospholipids

Group 4 = *Centella asiatica* complex with phospholipids

Group 5 = *Coleus forskolii* standardized extract (20% forskolin)

Group 6 = Ethyl ximeninate

Group 7 = Composition of Example 2

The compositions contained the same excipients.

1000 mg of cream were applied on the thigh of each woman twice a day for 30 days in a row. On day 31, the effect was evaluated measuring the skin macrorelief ("orange peel effect") through profilometry on digital imaging of pinched thighs analysis according to Bertin C. et al., *J. Cosmet. Sci.*, 52, 199-210, 2001. The effect was also evaluated measuring high thigh circumference according to Gasbarro V. and Vettorello G.F., *Cosmetics and Toiletries*, 107, 64-66, 1992.

The results reported in Tables 1 and 2 show that the composition of Example 2 is unexpectedly and significantly higher than that of the single components.

Table 1 – Effect of the composition of Example 2 on profilometric analysis of thigh macrorelief (Rz)

Treatment	T <sub>0</sub>	T <sub>30</sub>
Group 1	7.27±0.7	7.29±0.8
Group 2	6.99±0.6	6.84±0.6
Group 3	7.20±0.5	6.31±0.5
Group 4	7.24±0.6	6.19±0.6
Group 5	7.28±0.3	6.62±0.6
Group 6	7.35±0.4	6.33±0.5
Group 7	7.06±0.7	2.99±0.4**

Rz = roughness parameter

\*\* p < 0.001 vs basal Student's "t" test

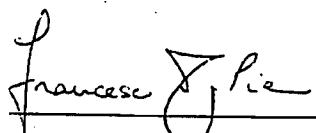
Table 2 - Effect of the composition of Example 2 on left thigh circumference .

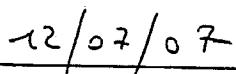
Treatment	T <sub>0</sub>	T <sub>30</sub>
Group 1	56.0±0.2	56.2±0.3
Group 2	55.9±0.1	56.0±0.2
Group 3	55.2±0.3	54.6±0.2
Group 4	54.8±0.2	54.5±0.1
Group 5	55.9±0.1	55.1±0.1
Group 6	53.7±0.2	52.9±0.3
Group 7	56.1±0.2	52.3±0.2*

\* p < 0.01 Student's "t" test

Thus, in view of the results reported in Tables 1 and 2, declarant believes that the experimental results show that the claimed invention exhibits unexpected results.

The undersigned declare further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
\_\_\_\_\_  
Name of Declarant

  
\_\_\_\_\_  
Date

Dr. Francesco Di Pierro, PhD

## **CURRICULUM VITAE**

Dr. Di Pierro was born in Turin (Italy) in 1967 and educated at the town's university. He graduated in Biology from the Faculty of Science (1990) and was awarded the professional qualification of a Biologist (1991). He also received his PhD in Immunology from the Faculty of Medicine and Surgery (1996).

From 1988, he took part in a number of basic and preclinical research programmes, above all in the fields of pharmacology and immunology:

- 1) he studied the etiopathogenesis and biology of leukemic meningosis - a frequent complication of acute lymphatic leukaemia - at the Anatomy and Pathologic Histology Department of "R. Margherita" children's hospital (1988-1990);
- 2) he worked on a project aimed to genic treatment of tumours and development of experimental antitumoral vaccines at the Immunology Institute of Turin University (1991-1993);
- 3) as head of the immunopharmacology laboratory of the Research Centre of Italfarmaco, Milan, he worked on the development of new immunosuppressive molecules for the treatment of transplant rejection, multiple sclerosis and rheumatoid arthritis, as well as on the study of the basic mechanisms that are responsible for septic shock (1993-1996).

As a Senior Scientist at the Scientific Department of Indena since 1996, he has been engaged in the study of the pharmacological aspects of medicinal plant-based products and particularly in the research and development of new herbal remedies in the pharmaceutical, cosmetic and dietary supplement sectors.

As SIIT, Scientific Director he has involved in researching and developing new finished product in the dietetic and in the pharmaceutical sector.

He is the author of 26 specialist papers, published in international medical research reviews and mostly devoted to immunology, oncology, haematology, and phytotherapy and over 200 popular scientific articles which have appeared in the leading Italian newspapers and magazines.

Dr. Di Pierro has taken active part in several congresses (with about 20 speeches); held a number of lectures on experimental immunology and has often been invited by pharmaceutical companies and universities to hold seminars.

Scientific papers

01. Francesco Novelli, Mirella Giovarelli, Federica Cavallo, **Francesco Di Pierro**, Mario Zucca, Stefania Vai, Gianni Garotta, Guido Forni.  
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11. **Francesco Di Pierro**, Federica Cavallo, Federica Pericle, Sabrina Bertini, Mirella Giovarelli and Guido Forni.  
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22. Giorgio Bertolini, Mario Aquino, Mauro Biffi, Gaetano d'Atri, **Francesco Di Pierro**, Francesco Ferrario, Paolo Mascagni, Flavio Somenzi, Andrea Zaliani and Flavio Leoni.  
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